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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,540	06/21/2001	Robert Klein	R-193	5814

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	9

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/887,540	Applicant(s) KLEIN, ROBERT	
	Examiner Michael Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: detailed action/notice to comply.

DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The sequence in Fig. 3A-3B does not have a SEQ ID NO**. Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing."

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, 2 and 3, drawn to a construct encoding low density lipoprotein-related protein 5 and a selectable marker, classified in class 435, subclass 320.1.

II. Claim 1-4, drawn to a knockout construct comprising two nucleic acid sequences homologous to the low density lipoprotein-related protein 5 gene, and a selectable marker inserted in between the two sequences, and methods of making such a construct, classified in class 435, subclass 320.1.

III. Claims 5-7, 9, drawn to cells having a disruption in the low density lipoprotein-related protein 5 gene comprising a knockout construct, classified in class 435, subclass 325.

IV. Claims 8, 10, drawn to a transgenic mouse having a disruption in a low density lipoprotein-related protein 5 gene, and a method of making the mouse, classified in class 800, subclass 8.

V. Claims 11, 12, drawn to methods of using animals having a disruption of a low density lipoprotein-related protein 5 to test compounds, classified in class 800, subclass 3.

VI. Claims ~~13 and 14~~ 13-15, drawn to a method identifying compounds by contacting cells have a disruption of a low density lipoprotein-related protein 5 gene with test agents, classified in class 530, subclass 350.

VII. Claim ~~15~~ 16, drawn to low density lipoprotein-related protein 5 modulators, classified in various classes and subclasses.

This application contains the following inventions or groups of inventions that are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Groups I and II are patentably distinct because the construct of Group I is for expressing DNA encoding low density lipoprotein-related protein 5 while the construct of Group II is for preventing expression of the low density lipoprotein-related protein 5

gene. The structure and mode of operation for each construct is mutually exclusive. The construct of group I is not required for the construct of Group II and vice versa.

Inventions I and III are patentably distinct because the construct is capable of causing overexpression of low density lipoprotein-related protein 5 while the cells have a disruption in a low density lipoprotein-related protein 5 gene. The protocol and reagents for the construct and cells are materially distinct and separate. The construct does not require the cells and the cells do not require the construct.

Inventions I and IV are patentably distinct because the construct is capable of causing overexpression of low density lipoprotein-related protein 5 while the mice have a disruption in a low density lipoprotein-related protein 5 gene. The protocol and reagents for the construct and mice are materially distinct and separate. The construct does not require the mice and the mice do not require the construct.

Inventions I and V are patentably distinct because the construct is capable of causing overexpression of low density lipoprotein-related protein 5 while the method requires mice have a disruption in a low density lipoprotein-related protein 5 gene. The protocol and reagents for the construct and the method are materially distinct and separate. The construct does not require the method and the method does not require the construct.

Inventions I and VI are patentably distinct because the construct is capable of causing overexpression of low density lipoprotein-related protein 5 while the method requires cells have a disruption in a low density lipoprotein-related protein 5 gene. The protocol and reagents for the construct and the method are materially distinct and

separate. The construct does not require the method and the method does not require the construct.

Groups I and VII are patentably distinct because the construct is capable of causing overexpression of low density lipoprotein-related protein 5 while the agent is capable of modulating low density lipoprotein-related protein 5 gene expression. The protocol and reagents for using the construct and the agent are materially distinct and separate. The construct does not require the agent and the agent does not require the construct.

Inventions II and III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful to make transgenic mice and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions II and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the

intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful in making cells having a disruption in a low density lipoprotein-related protein 5 gene and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions II and V are patentably distinct because the construct is used to disrupt a low density lipoprotein-related protein 5 gene while the administering agents to mice is for identifying agents that modulate low density lipoprotein-related protein 5 activity. The protocol and reagents for the construct and the method are materially distinct and separate. The construct does not require the method and the method does not require the construct.

Inventions II and VI are patentably distinct because the construct is used to disrupt a low density lipoprotein-related protein 5 gene while the administering agents to cells is for identifying agents that modulate low density lipoprotein-related protein 5 activity. The protocol and reagents for the construct and the method are materially

distinct and separate. The construct does not require the method and the method does not require the construct.

Groups II and VII are patentably distinct because the construct is used to disrupt a low density lipoprotein-related protein 5 gene while the agent is capable of modulating low density lipoprotein-related protein 5 gene expression. The protocol and reagents for using the construct and the agent are materially distinct and separate. The construct does not require the agent and the agent does not require the construct.

Inventions III and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the cells as an intermediate product (used to make the transgenics) are deemed to be useful for isolating protein and for use in *in vitro* assays and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. When the animals are the intermediate product and cells are isolated from the animal, the animals are useful as a model for the lack of low density lipoprotein-related protein 5 expression *in vivo*. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions III and V are patentably distinct because the cells can be used to isolate proteins while the method of using the mouse can be for isolating compounds that treat disease. The cells are not required for the method and the method does not require the cells.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be used with transgenic animals and the product can be used to make transgenic animals.

Groups III and VII are patentably distinct because the cells are used to make transgenics while the agent is capable of modulating low density lipoprotein-related protein 5 gene expression. The protocol and reagents for using the cells and the agent are materially distinct and separate. The cells do not require the agent and the agent does not require the cells.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can

be performed with cells *in vitro* and do not require the mice, and the mice can be used for the isolation of cells for *in vitro* assays.

Inventions IV and VI are patentably distinct because the mouse can be used as a model of disease while the method of using cells can be used to identify agents that modulate low density lipoprotein-related protein 5 *in vitro*. The mouse does not require the method and the method does not require the mouse.

Inventions IV and VII are patentably distinct because the mouse can be used as a model of disease while the modulator of a low density lipoprotein-related protein 5 gene can be used to treat a patient. The protocols and reagents for mice and for using a modulator to treat disease are materially distinct and separate. The mouse does not require the modulator and the modulator does not require the mouse.

Groups V and VI are patentably distinct because administering agents to a mouse is a model of disease while administering agents to cells *in vitro*. The protocols and reagents required for testing compounds *in vitro* and *in vivo* are materially distinct and separate. The method of administering an agent to a mouse does not require administering an agent to cells and vice versa.

Groups V or VI and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be identified using cells or

using transgenics, and the process can be used to identify materially distinct products that modulate low density lipoprotein-related protein 5 expression.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER